REMARKS

On pages 4-7 of the Office Action, the Examiner rejected claims 30-54 under 35 U.S.C. § 103(a) as being unpatentable over, Mehta et al., United States Patent No. 5,837,284 ("Mehta et al.") in view of Mulye, United States Patent No. 6,475,493 ("Mulye") and Beiman et al., United States Patent No., 6,312,728 (Beiman et al.).

Reconsideration is requested.

The invention recited in the currently pending claims is a controlled release methylphenidate tablet that comprises two primary elements: 1) an immediate release methylphenidate coating and 2) a controlled release methylphenidate tablet core. The controlled release methylphenidate tablet core comprises a compressed mixture of methylphenidate and a hydrogel polymer and an enteric coating around the compressed mixture. This unique dosage form is further required to exhibit two distinct methylphenidate plasma peaks when the tablet is administered to humans. In addition, the claimed tablet must exhibit a controlled release of the methylphenidate when tested in a pH 7.5 media.

Applicants respectfully submit the presently claimed formulation is patentable over the references of record because none of the references either alone or combined disclose or suggest a methylphenidate tablet that employs a compressed admixture of methylphenidate and a hydrogel polymer which is subsequently coated with an enteric polymer to provide controlled release of the methylphenidate over an extended period of time when tested in high pH environments.

Applicants submit that the present claims are patentable over the cited references either alone or combined because the cited references fail to disclose or suggest the use of a hydrogel polymer in the core of an controlled release tablet. As indicated above, the present claims all

require a compressed core comprising methylphenidate and a hydrogel polymer wherein the compressed mixture is coated with an enteric polymer. The claims further require that the methylphenidate is released in a controlled manner when exposed to a high pH environment.

As discussed in the prior Amendments, the Mehta reference discloses oral methylphenidate dosage forms that employ immediate release pellets and controlled release pellets. Applicants again gratefully acknowledge the Examiner's prior indication that the Mehta fails to disclose the use of an enteric polymer. Applicants also respectfully submit, the Mehta reference fails to disclose the use of a compressed admixture of methylphenidate and a hydrogel polymer to control the release of the methylphenidate from the core as required by the pending claims.

On page 3 of the Office Action the Examiner points to Example 1 of Mehta et al. as teaching the compressed core containing a hydrogel polymer and methylphenidate. Specifically, the Office Action recites that "Mehta teaches a preparation in the invention in which a 10 percent solution of hydroxypropyl methylcellulose (HPMC) was mixed in a solution of methylphenidate of which was then coated with a sealant (Example 1), which reads on an admixture of methylphenidate and a hydrogel polymer in the core". Applicants submit that the Examiner is in error based on this review of Mehta et al. A detailed review of Example 1 of Mehta et al. shows that Example 1 teaches use of "HPMC E-6 from Dow Chemicals, Midland, Mich". HPMC E-6 is not a "hydrogel polymer". In contrast, HPMC E-6 is a very low viscosity polymer. See Exhibit A, Rowe et al., *Handbook of Pharmaceutical Excipients*, p. 297-300 (4th Ed. 2003), which indicates that HPMC E-6 has a viscosity in the range of 5-7 mPa's.

The specification of the present application specifically teaches the use of hydrogel polymers such as Methocel K-100M Premium (See Examples 1-4 of the present specification).

This hydrogel polymer has a very high viscosity, in the range of 80,000 to 120,000 mPa's as can be seen at page 298 of Exhibit A. A high viscosity is required for a polymer to be considered a hydrogel polymer. Further the hydrogel polymer assists in the production of the claimed release characteristics of the present invention.

Mehta et al. does not teach a controlled release tablet core containing methylphenidate and a hydrogel polymer, but the combination of methylphenidate and a low viscosity polymer.

The Examiner references Mulye and Beiman et al. to alleviate these deficiencies. Applicants submit that Mulye and Beiman et al. do not fill the gaps left by Mehta et al. , and more particularity teach away from the claims of the present invention.

The addition of the Mulye reference to the Mehta reference fails to suggest to an individual of ordinary skill the controlled release methylphenidate tablet recited in the currently pending claims. In fact, the Mulye reference would lead an individual of ordinary skill away from the presently claimed invention. The Mulye reference discloses multiparticulate dosage forms, not compressed tablet dosage forms, wherein the release of the drug is controlled by a coating comprising an enteric polymer and a water insoluble polymer.

Next the Examiner references Beiman et al. to alleviate the remaining deficiencies of Mehta et al. and Mulye. The addition of the Beiman reference to the teachings of the Mehta and Mulye references also fails to overcome the deficiencies of the Mehta/Mulye proposed combination. First, the Beiman reference teaches multiparticulate dosage forms but fails to mention methylphenidate. It is respectfully submitted that an individual of ordinary skill would not look to the Beiman reference for guidance on preparing a controlled release methylphenidate tablets due to the lack of a methylphenidate dosage from disclosure.

Applicants submit that combining the disclosures in Mehta et al., Mulye and Beiman et al. to arrive at the present invention is based on improper hindsight and cherry picking of selected phrase from the prior art in view of the teaching in the present application. Further, when the cited references are read in their proper context they do not disclose the present invention and actually teach away from the present invention. Because these references teach dosage forms using low viscosity polymers in multiparticulate formulations, not compressed tablet formulations containing hydrogel polymers, they teach away from the claims of the present invention.

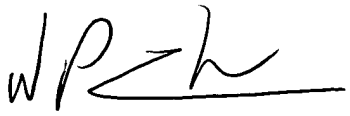
Further, because these references do not teach or suggest the composition of the presently claimed invention, the specifically claimed release profiles of the present invention are not properties directly attributable to the prior art.

Therefore, because the cited prior art references do not disclose or suggest the combination of methylphenidate and a hydrogel polymer in the core of a controlled release tablet it is requested that the above 103(a) rejection be withdrawn.

Applicants submit that the Examiner's statement on page 4 of the Office Action that all claims should be construed as "comprising" claims is in error. Independent claim 47 (and claims 48-54, which are dependent thereon) explicitly recite "consisting essentially of", not comprising language. As discussed above in detail the novel characteristics of the present invention have been detailed and the claim language in claims 47-54 is unambiguous with regard to the "consisting essentially of" language. It is therefore requested that the Examiner examine these claims appropriately.

Based upon the above remarks, Applicants respectfully submit that claims 30-54 are allowable over the prior art and that the present application is in proper form for allowance. Favorable consideration and early allowance is respectfully requested and earnestly solicited.

Respectfully submitted,



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